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WASHINGTON, D.C. 20231  
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Bib Data Sheet

CONFIRMATION NO. 8943

<b>SERIAL NUMBER</b> 09/701,558	<b>FILING DATE</b> 12/05/2000 <b>RULE</b>	<b>CLASS</b>	<b>GROUP ART UNIT</b> 3763	<b>ATTORNEY DOCKET NO.</b> MUR-024-USA-PCT
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## APPLICANTS

Naruhito Higo, Tsukuba-shi, JAPAN;  
Hirotochi Adachi, Tsukuba-shi, JAPAN;  
Noriyuki Kuzumaki, Tsukuba-shi, JAPAN;

RECEIVED

JUL 19 2001

TECHNOLOGY CENTER R3700

## \*\* CONTINUING DATA \*\*\*\*\*

THIS APPLICATION IS A 371 OF PCT/JP99/02623 05/19/1999

## \*\* FOREIGN APPLICATIONS \*\*\*\*\*

JAPAN 10-174024 06/05/1998

## IF REQUIRED, FOREIGN FILING LICENSE GRANTED

\*\* 02/03/2001

Foreign Priority claimed <input type="checkbox"/> yes <input type="checkbox"/> no	<b>STATE OR COUNTRY</b> JAPAN	<b>SHEETS DRAWING</b> 2	<b>TOTAL CLAIMS</b> 15	<b>INDEPENDENT CLAIMS</b> 4
35 USC 119 (a-d) conditions met <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance				
Verified and Acknowledged Examiner's Signature _____ Initials _____				

## ADDRESS

Townsend & Banta  
Suite 500  
1225 Eye Street NW  
Washington ,DC 20005

## TITLE

Iontophoresis device structure and method for detecting physiological substance

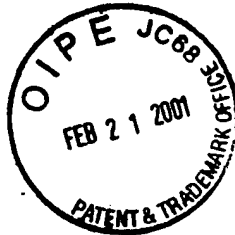
<b>FILING FEE RECEIVED</b> 940	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees
		<input type="checkbox"/> 1.16 Fees ( Filing )
		<input type="checkbox"/> 1.17 Fees ( Processing Ext. of time )
		<input type="checkbox"/> 1.18 Fees ( Issue )
		<input type="checkbox"/> Other _____
		<input type="checkbox"/> Credit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
N. Higo, et al.

Serial No.: 09/701,558

Filed: December 5, 2000



Art Unit: To Be Assigned

Examiner: To Be Assigned

For: Iontophoresis Device Structure  
And Method For Detecting Physiological Substance

REQUEST FOR CORRECTED FILING RECEIPT

RECEIVED

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

JUL 19 2001

TECHNOLOGY CENTER R3700

Sir:

Applicants' counsel is in receipt of the PTO Filing Receipt for the above identified pending patent application, a copy of which is attached hereto. Upon verifying the accuracy of the data presented on the Filing Receipt it was noted that there are errors in the title for this invention which were introduced by the Patent Office. As evidenced by the attached copy of the Transmittal, Declaration and Power of Attorney, and first page of the original specification which contains the title, the title "Iontophoresis Device Structure And Method For Detecting Physiological Substance" is misspelled as "Iontophoresis Device Structural Body And Method For Detecting In-vivo Component" on the Filing Receipt.

It is respectfully requested that the Patent Office records be corrected to reflect the correct title and that the undersigned be provided with a corrected Filing Receipt.

Respectfully submitted,

TOWNSEND & BANTA

*Donald E. Townsend, Jr.*  
Donald E. Townsend, Jr.  
Reg. No. 43,198

Date: February 12, 2001

TOWNSEND & BANTA  
Suite 500  
1225 Eye Street, N.W.  
Washington, D.C. 20005  
(202) 682-4727



# UNITED STATES PATENT AND TRADEMARK OFFICE

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WASHINGTON, D.C. 20231  
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/701,558	12/05/2000	1743	940	MUR-024- USA-PCT	2	15	4

Townsend & Banta  
Suite 500  
1225 Eye Street NW  
Washington, DC 20005

## FILING RECEIPT



\*OC000000005732819\*

Date Mailed: 02/05/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

### Applicant(s)

Naruhito Higo, Tsukuba-shi, JAPAN;  
Hirotochi Adachi, Tsukuba-shi, JAPAN;  
Noriyuki Kuzumaki, Tsukuba-shi, JAPAN;

### Continuing Data as Claimed by Applicant

THIS APPLICATION IS A 371 OF PCT/JP99/02623 05/19/1999

### Foreign Applications

JAPAN 10-174024 06/05/1998

If Required, Foreign Filing License Granted 02/03/2001

### Title

Iontophoresis device structural body and method for detecting in-vivo component

### Preliminary Class

422

**Data entry by : BARRETO, NGA**

**'Team':** OIPE

**Date:** 02/05/2001

~~[REDACTED]~~

**LICENSE FOR FOREIGN FILING UNDER**  
**Title 35, United States Code, Section 184**  
**Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 36 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**PLEASE NOTE the following information about the Filing Receipt:**

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 600 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

Assistant Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, DC 20231

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

MUR-024-USA-PCT

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.  
PCT/JP99/02622

INTERNATIONAL FILING DATE  
May 19, 1999

PRIORITY DATE CLAIMED  
June 3, 1998

TITLE OF INVENTION Iontophoresis Device Structure And  
Method For Detecting Physiological Substance

APPLICANT(S) FOR DO/EO/US

Naruhito Hico, Hirotochi Adachi and Noriyuki Kuzumaki

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 16 below concern document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: Claim For Priority  
Transmittal of Amendment filed on December 24,  
1999 under Article 34 of pages 9 and 33  
(English translation of translated pages 9  
and 33 only)

## DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

IONTOPHORESIS DEVICE STRUCTURE AND  
METHOD FOR DETECTING PHYSIOLOGICAL SUBSTANCE

the specification of which is ☒ attached and/or ☐ was filed on ..... as Application Serial No. .... and was amended on (if applicable) .....  
☒ international (PCT) application No. PCT/JP99/02623 filed May 19, 1999 and as amended on Dec. 24, 1999 (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED UNDER 35 U.S.C. §119
JAPAN	10/174024	June 5, 1998	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NUMBER	DATE OF FILING	STATUS (Patented, Pending, Abandoned)

I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Law Offices of Townsend & Banta: Donald E. Townsend, Registration No. 22,069; ~~Robert P. Banta, Registration No. 43,198~~; and Donald E. Townsend, Jr., Registration No. 43,198

Please address all correspondence to the Law Offices of Townsend & Banta, Suite 500, 1225 Eye Street, N.W., Washington, D.C. 20005

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR HIGO, Naruhito	INVENTOR'S SIGNATURE <i>Naruhito Higo</i>	DATE October 12, 2000
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN	CITIZENSHIP JAPANESE	
POST OFFICE ADDRESS same as residence		
FULL NAME OF SECOND JOINT INVENTOR, IF ANY ADACHI, Hiroto	INVENTOR'S SIGNATURE <i>Hiroto Adachi</i>	DATE October 25, 2000
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN	CITIZENSHIP JAPANESE	
POST OFFICE ADDRESS same as residence		

Listing of Inventors Continued on Page 2 hereof. ☒ Yes ☐ No

## SPECIFICATION

### IONTOPHORESIS DEVICE STRUCTURE AND METHOD FOR DETECTING PHYSIOLOGICAL SUBSTANCE

5

#### TECHNICAL FIELD

The present invention relates to an iontophoresis device structure and a method for detecting a physiological substance suitable to be used in diagnosis and examination on the medical  
10 field.

#### BACKGROUND ART

Various methods have been used for diagnosis of diseases. For example, biochemical examination of blood where diagnose  
15 is performed by analyzing blood components, a variety of diagnostic markers, cells and the like after invasively collecting blood, pathological examination where vital histological examination of cancer tissues etc. is invasively performed or examined whether cell levels are normal or not,  
20 and examinations by analyzing urine, stool, saliva, etc. after collection of urine, stool, saliva, etc. In these methods in the present state, medical doctors, nurses or clinical technologists collect blood etc. by injectors or cut off living tissues by a sharp scalpel or collect urine etc. in a specific  
25 container in cooperation with patients.

Since a tumor, particularly a malignant melanoma is a disease which has an extremely poor prognosis and has both extremely